

## **REMARKS**

This amendment responds to the non-final Office Action mailed February 17, 2006. Previously, Claims 1-42 were pending. In the instant amendment, Claims 2-11 have been canceled without prejudice. Claims 1, 22, 32, 33 and 38 have been amended. After entry of the instant amendment, Claims 1 and 12-42 will be pending and under consideration in the instant application.

Applicants kindly thank the Patent Office for the indication that claims 18, 25, 31, 37, and 38 are free of the art of record and for the thoroughness of the examination of the claimed subject matter.

### **I. AMENDMENTS TO THE SPECIFICATION**

The specification has been amended to delete an embedded hyperlink at pages 13 and 18. Applicants submit that these amendments do not introduce any new matter and are fully supported by the specification as filed. Therefore, entry and consideration thereof is respectfully requested.

### **II. AMENDMENTS TO THE CLAIMS**

In the instant amendment, Claims 2-11 have been canceled without prejudice to Applicant's right to pursue the canceled subject matter in one or more related divisional, continuation and continuation-in-part patent applications.

Claims 1, 22, 32, 33, and 38 have been amended. Support for the amendments to Claim 1 can be found, for example, in the specification, from page 4, line 25, to page 5, line 2, and at page 5, line 21. Claim 1 has additionally been amended to exclude certain mutations from the claimed subject matter. Each of the mutations affirmatively excluded from the claims was originally described in the application as filed at, for example, page 7, line 24, page 44, lines 13-14, and in Table 2. Accordingly, the amendment excluding these mutations is fully supported by the application as filed and presents no new matter. *See In re Johnson*, 194 USPQ 187 (CCPA 1977) and M.P.E.P § 2173.05(j).

Support for the amendment to claim 22 may be found, for example, in claim 22 as filed. Support for the amendments to claims 32 and 33 may be found, for example, in the specification at page 7, lines 21-22. Claim 38 has been amended to depend from Claim 37 and is thus supported by, for example, claim 38 as filed..

Applicants submit that these amendments do not introduce any new matter and are fully supported by the specification as filed. Therefore, entry and consideration thereof is respectfully requested under 37 C.F.R. § 1.111..

### **III. THE OBJECTIONS TO THE SPECIFICATION**

The specification is objected to because it contains an embedded hyperlink and/or other forms of browser-executable code. Applicants submit that this objection is obviated in view of the amendments to the specification. Therefore, Applicants respectfully request that the objection to the specification be withdrawn.

### **IV. THE OBJECTIONS TO THE CLAIMS**

Claim 7 stands objected to because it refers to mutations identified by reference to the Tables in the specification. Applicants submit that this objection is obviated in view of the cancellation of the claim. Therefore, Applicants respectfully request that the objection to the claim be withdrawn.

Claims 18, 25, 31, 37, and 38 stand objected to because the claims, while reciting allowable subject matter, depend from rejected claims. Applicants believe that the claims from which claims 18, 25, 31, 37, and 38 have been placed in condition for allowance in the present paper. Accordingly, Applicants respectfully request that the objection to claims 18, 25, 31, 37, and 38 be withdrawn.

### **V. THE REJECTION OF CLAIM 38 UNDER 35 U.S.C. §112, SECOND PARAGRAPH**

Claim 38 stands rejected under 35 U.S.C. § 112, second paragraph for alleged indefiniteness because it depends upon itself. Claim 38 has been amended to depend from Claim 37. Applicants submit that this objection is obviated in view of the amendment to the claim. Therefore, Applicants respectfully request that the rejection of Claim 37 be withdrawn.

### **VI. THE REJECTION OF CLAIMS UNDER 35 U.S.C. §102(b)**

#### **A. The Rejection of Claims 1, 2, 12, 22, 26, 36 and 42 over Robinson *et al.***

Claims 1, 2, 12, 22, 26, 36 and 42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Robinson *et al.*, 2000, *AIDS RES. & HUMAN RETROVIRUS* 16:1149-56 (“Robinson *et al.*”). Claim 1 has been amended. Applicants respectfully submit that the rejection of Claims 1, 2, 12, 22, 26, 36 and 42 is moot in view of the amendments to Claim 1 as Robinson *et al.* does not teach each and every element of the invention as presently

claimed. Therefore, Robinson *et al.* cannot anticipate Claims 1, 2, 12, 22, 26, 36, and 42 as presently pending. *See In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir., 1990).

Accordingly, Applicants respectfully request that the rejection of Claims 1, 2, 12, 22, 26, 36 and 42 as being anticipated by Robinson *et al.* under 35 U.S.C. § 102(b) be withdrawn.

**B. The Rejection of Claims 1, 2, 7, 8, 12, 14, 22, 26 and 42 over Schmidt *et al.***

Claims 1, 2, 7, 8, 12, 14, 22, 26 and 42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Schmidt *et al.*, 2000, *ANTIMICROBIAL AGENTS AND CHEMOTHERAPY* 44(11):3213-16 (“Schmidt *et al.*”). Applicants submit that the rejection of Claims 7 and 8 is moot in view of their cancellation.

Applicants respectfully traverse the rejection of Claims 1, 2, 12, 14, 22, 26 and 42. The Patent Office alleges that Schmidt *et al.* disclosed that the amprenavir resistance profile of HIV protease includes mutation 32I, 33F, 54V and 82A/F. Except for the mutation 54V, Schmidt *et al.* explicitly states that the mutation 32I, 33F or 82A/F was not associated with reduced sensitivity to amprenavir, because data regarding the association between these mutations and altered sensitivity to amprenavir did not achieve statistical significance. *See* Schmidt *et al.*, at page 3215, left column, the second full paragraph. Further, Applicant respectfully submit that the rejection with regard to the I54V mutation is moot in view of the amendment to claim 1. Therefore, Applicants respectfully submit that Schmidt *et al.* does not teach each of and every element of Claims 1, 2, 12, 14, 22, 26 and 42 as amended and therefore cannot anticipate such claims. *See In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir., 1990).

Thus, Applicants respectfully submit that Schmidt *et al.* does not anticipate amended Claims 1, 2, 7, 8, 12, 14, 22, 26 and 42. Accordingly, Applicants respectfully request that the rejection of Claims 1, 2, 7, 8, 12, 14, 22, 26 and 42 as being anticipated by Schmidt *et al.* under 35 U.S.C. § 102(b) be withdrawn.

**C. The Rejection of Claims 1, 7, 12, 19, 22, 26 and 42 over Deeks *et al.***

Claims 1, 7, 12, 19, 22, 26 and 42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Deeks *et al.*, 1999, *J. INFECTIOUS DISEASE* 179:1375-81 (“Deeks *et al.*”). Applicants submit that the rejection of Claim 7 is moot in view of their cancellation.

Applicants respectfully traverse the rejection of Claims 1, 12, 19, 22, 26 and 42 as anticipated by Deeks *et al.* Applicants respectfully submit that Deeks *et al.* does not anticipate amended Claims 1, 12, 19, 22, 26 and 42 because Deeks *et al.* does not teach each

and every element of Claims 1, 12, 19, 22, 26 and 42 as presently amended. For instance, Deeks *et al.* does not teach a method for determining whether a human immunodeficiency virus type 1 (HIV-1) has an increased likelihood of having a reduced susceptibility to treatment with amprenavir. In addition, Deeks *et al.* does not teach that the presence of any particular mutation in HIV protease indicates that HIV-1 has an increased likelihood of having reduced susceptibility to treatment with amprenavir. Thus, Deeks *et al.* does not teach each and every element of Claims 1, 12, 19, 22, 26 and 42 and therefore cannot anticipate such claims. *See In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir., 1990).

Accordingly, Applicants respectfully request that the rejection of Claims 1, 7, 12, 19, 22, 26 and 42 as being anticipated by Deeks *et al.* under 35 U.S.C. § 102(b) be withdrawn.

**D.     The Rejection of Claims 1, 7, 21, 22, 29, 32, 33, 36 and 39-42 over Carrillo *et al.***

Claims 1, 7, 21, 22, 29, 32, 33, 36 and 39-42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Carrillo *et al.*, 1998, *J. VIROLOGY* 72(9):7532-41 (“Carrillo *et al.*”). Applicants respectfully traverse. Applicants submit that the rejection of Claim 7 is moot in view of its cancellation.

Applicants respectfully submit that Carrillo *et al.* does not anticipate amended Claims 1, 21, 22, 29, 32, 33, 36 and 39-42 because Carrillo *et al.* does not teach each and every element of Claims 1, 21, 22, 29, 32, 33, 36 and 39-42 as presently amended. For instance, Carrillo *et al.* does not teach a method for determining whether a human immunodeficiency virus type 1 (HIV-1) has an increased likelihood of having a reduced susceptibility to treatment with amprenavir. In addition, Carrillo *et al.* does not teach that the presence of any particular mutation of HIV protease indicates that HIV-1 has an increased likelihood of having reduced susceptibility to treatment with amprenavir. Thus, Carrillo *et al.* does not does not teach each and every element of Claims 1, 21, 22, 29, 32, 33, 36 and 39-42 and therefore cannot anticipate such claims. *See In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir., 1990).

Accordingly, Applicants respectfully request that the rejection of Claims 1, 7, 21, 22, 29, 32, 33, 36 and 39-42 as being anticipated by Carrillo *et al.* under 35 U.S.C. § 102(b) be withdrawn.

**E.     The Rejection of Claims 1, 7, 12, 19, 22, 29, 30, 36 and 42 over Condra *et al.***

Claims 1, 7, 12, 19, 22, 29, 30, 36 and 42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Condra *et al.*, 1996, *J. VIROLOGY* 72(9):7532-41 (“Condra *et al.*”). Applicants respectfully traverse. Applicants submit that the rejection of Claim 7 is moot in view of its cancellation.

Applicants respectfully submit that Condra *et al.* does not anticipate amended Claims 1, 12, 19, 22, 29, 30, 36 and 42 because Condra *et al.* does not teach each and every element of Claims 1, 12, 19, 22, 29, 30, 36 and 42 as presently amended. For instance, Condra *et al.* does not teach a method for determining whether a human immunodeficiency virus type 1 (HIV-1) has an increased likelihood of having a reduced susceptibility to treatment with amprenavir. In addition, Condra *et al.* does not teach that the presence of any particular mutation of HIV protease indicates that HIV-1 has an increased likelihood of having reduced susceptibility to treatment with amprenavir. Thus, Condra *et al.* does not does not teach each and every element of Claims 1, 12, 19, 22, 29, 30, 36 and 42 and therefore cannot anticipate such claims.

Accordingly, Applicants respectfully request that the rejection of Claims 1, 7, 12, 19, 22, 29, 30, 36 and 42 as being anticipated by Condra *et al.* under 35 U.S.C. § 102(b) be withdrawn.

**F.     The Rejection of Claims 1, 7, 12, 23, 36 and 42 over Croteau *et al.***

Claims 1, 7, 12, 23, 36 and 42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Croteau *et al.*, 1996, *J. VIROLOGY* 71(2):1089-96 (“Croteau *et al.*”). Applicants respectfully traverse. Applicants submit that the rejection of Claim 7 is moot in view of its cancellation.

Applicants respectfully submit that Croteau *et al.* does not anticipate amended Claims 1, 12, 23, 36 and 42 because Croteau *et al.* does not teach each and every element of Claims 1, 12, 23, 36 and 42 as presently amended. For instance, Croteau *et al.* does not teach a method for determining whether a human immunodeficiency virus type 1 (HIV-1) has an increased likelihood of having a reduced susceptibility to treatment with amprenavir. In addition, Croteau *et al.* does not teach that the presence of any particular mutation of HIV protease indicates that HIV-1 has an increased likelihood of having reduced susceptibility to treatment with amprenavir. Thus, Croteau *et al.* does not does not teach each and every

element of Claims 1, 12, 23, 36 and 42 and therefore cannot anticipate such claims. *See In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir., 1990).

Accordingly, Applicants respectfully request that the rejection of Claims 1, 7, 12, 23, 36 and 42 as being anticipated by Croteau *et al.* under 35 U.S.C. § 102(b) be withdrawn.

**G. The Rejection of Claims 1, 7, 12, 15, 16 and 42 over Jørgensen *et al.***

Claims 1, 7, 12, 15, 16 and 42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Jørgensen *et al.*, 2001, Accession No. CAB94359. Applicants respectfully traverse. Applicants submit that the rejection of Claim 7 is moot in view of its cancellation.

Applicants respectfully submit that Jørgensen *et al.* does not anticipate amended Claims 1, 12, 15, 16 and 42 because Jørgensen *et al.* does not teach each and every element of Claims 1, 12, 15, 16 and 42 as presently amended. For instance, Jørgensen *et al.* does not teach a method for determining whether a human immunodeficiency virus type 1 (HIV-1) has an increased likelihood of having a reduced susceptibility to treatment with amprenavir. In addition, Jørgensen *et al.* does not teach that the presence of any particular mutation of HIV protease indicates that HIV-1 has an increased likelihood of having reduced susceptibility to treatment with amprenavir. Thus, Jørgensen *et al.* does not does not teach each and every element of Claims 1, 12, 15, 16 and 42 and therefore cannot anticipate such claims.

Accordingly, Applicants respectfully request that the rejection of Claims 1, 7, 12, 15, 16 and 42 as being anticipated by Jørgensen *et al.* under 35 U.S.C. § 102(b) be withdrawn.

**H. The Rejection of Claims 1, 7, 12, 24, 36 and 42 over Mascolini *et al.***

Claims 1, 7, 12, 24, 36 and 42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Mascolini *et al.*, *IAPAC Monthly* (August 2000) (“Mascolini *et al.*”). Applicants respectfully traverse. Applicants submit that the rejection of Claim 7 is moot in view of its cancellation.

Applicants respectfully submit that Mascolini *et al.* does not anticipate amended Claims 1, 12, 24, 36 and 42 because Mascolini *et al.* does not teach each and every element of Claims 1, 12, 24, 36 and 42 as presently amended. For instance, Mascolini *et al.* does not teach a method for determining whether a human immunodeficiency virus type 1 (HIV-1) has an increased likelihood of having a reduced susceptibility to treatment with amprenavir. In addition, Mascolini *et al.* does not teach that the presence of any particular mutation of HIV protease indicates that HIV-1 has an increased likelihood of having reduced susceptibility to treatment with amprenavir. Thus, Mascolini *et al.* does not does not teach each and every

element of Claims 1, 12, 24, 36 and 42 and therefore cannot anticipate such claims. *See In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir., 1990).

Accordingly, Applicants respectfully request that the rejection of Claims 1, 7, 12, 24, 36 and 42 as being anticipated by Mascolini *et al.* under 35 U.S.C. § 102(b) be withdrawn.

**I. The Rejection of Claims 1, 7, 12, 22, 26-28, 32-36 and 42 over Palmer *et al.***

Claims 1, 7, 12, 22, 26-28, 32-36 and 42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Palmer *et al.*, 1999, *AIDS* 71(2):661-67 (“Palmer *et al.*”). Applicants respectfully traverse. Applicants submit that the rejection of Claim 7 is moot in view of its cancellation.

Applicants respectfully submit that Palmer *et al.* does not anticipate amended Claims 1, 12, 22, 26-28, 32-36 and 42 because Palmer *et al.* does not teach each and every element of Claims 1, 12, 22, 26-28, 32-36 and 42 as presently amended. For instance, Palmer *et al.* does not teach a method for determining whether a human immunodeficiency virus type 1 (HIV-1) has an increased likelihood of having a reduced susceptibility to treatment with amprenavir. In addition, Palmer *et al.* does not teach that the presence of any particular mutation of HIV protease indicates that HIV-1 has an increased likelihood of having reduced susceptibility to treatment with amprenavir. Thus, Palmer *et al.* does not does not teach each and every element of Claims 1, 12, 22, 26-28, 32-36 and 42 and therefore cannot anticipate such claims.

Accordingly, Applicants respectfully request that the rejection of Claims 1, 7, 12, 22, 26-28, 32-36 and 42 as being anticipated by Palmer *et al.* under 35 U.S.C. § 102(b) be withdrawn.

**J. The Rejection of Claims 1, 7, 12, 13, 16 and 42 over Colonno *et al.***

Claims 1, 7, 12, 23, 36 and 42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Colonno *et al.*, 2000, Susceptibility Data on Clinical Isolates: NFV, available from the internet <URL:hivdb.stanford.edu/cgi-bin/GetResiData.cgi?type=allClinicalPhenotype&drug-NFV&class=PI&pos=84> (“Colonno *et al.*”). Applicants respectfully traverse. Applicants submit that the rejection of Claim 7 is moot in view of its cancellation.

Applicants respectfully submit that Colonno *et al.* does not anticipate amended Claims 1, 12, 13, 16 and 42 because Colonno *et al.* does not teach each and every element of Claims 1, 12, 13, 16 and 42 as presently amended. For instance, Colonno *et al.* does not

teach a method for determining whether a human immunodeficiency virus type 1 (HIV-1) has an increased likelihood of having a reduced susceptibility to treatment with amprenavir. In addition, Colonno *et al.* does not teach that the presence of any particular mutation of HIV protease indicates that HIV-1 has an increased likelihood of having reduced susceptibility to treatment with amprenavir. Thus, Colonno *et al.* does not teach each and every element of Claims 1, 12, 13, 16 and 42 and therefore cannot anticipate such claims. *See In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir., 1990).

Accordingly, Applicants respectfully request that the rejection of Claims 1, 7, 12, 13, 16 and 42 as being anticipated by Colonno *et al.* under 35 U.S.C. § 102(b) be withdrawn.

**K. The Rejection of Claims 1, 7, 12, 14, 17, 20, 22, 26-28, 36 and 42 over Kempf *et al.***

Claims 1, 7, 12, 14, 17, 20, 22, 26-28, 36 and 42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kempf *et al.*, 2001, *J. VIROLOGY* 75(16):7462-69 (“Kempf *et al.*”). Applicants respectfully traverse. Applicants submit that the rejection of Claim 7 is moot in view of its cancellation.

Applicants respectfully submit that Kempf *et al.* does not anticipate amended Claims 1, 12, 14, 17, 20, 22, 26-28, 36 and 42 because Kempf *et al.* does not teach each and every element of Claims 1, 12, 14, 17, 20, 22, 26-28, 36 and 42 as presently amended. For instance, Kempf *et al.* does not teach a method for determining whether a human immunodeficiency virus type 1 (HIV-1) has an increased likelihood of having a reduced susceptibility to treatment with amprenavir. In addition, Kempf *et al.* does not teach that the presence of any particular mutation of HIV protease indicates that HIV-1 has an increased likelihood of having reduced susceptibility to treatment with amprenavir. Thus, Kempf *et al.* does not teach each and every element of Claims 1, 12, 14, 17, 20, 22, 26-28, 36 and 42 and thus cannot anticipate such claims. *See In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir., 1990).

Accordingly, Applicants respectfully request that the rejection of Claims 1, 7, 12, 14, 17, 20, 22, 26-28, 36 and 42 as being anticipated by Kempf *et al.* under 35 U.S.C. § 102(b) be withdrawn.

**L. The Rejection of Claims 1, 7, 12, 15, 16 and 42 over Beerenwinkel *et al.***

Claims 1, 7, 12, 15, 16 and 42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Beerenwinkel *et al.*, 2002, Accession No. AAK32197 (“Beerenwinkel *et al.*”). Applicants respectfully traverse. Applicants submit that the rejection of Claim 7 is moot in view of its cancellation.

Applicants respectfully submit that Beerenwinkel *et al.* does not anticipate amended Claims 1, 12, 15, 16 and 42 because Beerenwinkel *et al.* does not teach each and every element of Claims 1, 12, 15, 16 and 42 as presently amended. For instance, Beerenwinkel *et al.* does not teach a method for determining whether a human immunodeficiency virus type 1 (HIV-1) has an increased likelihood of having a reduced susceptibility to treatment with amprenavir. In addition, Beerenwinkel *et al.* does not teach that the presence of any particular mutation of HIV protease indicates that HIV-1 has an increased likelihood of having reduced susceptibility to treatment with amprenavir. Thus, Beerenwinkel *et al.* does not teach each and every element of Claims 1, 12, 15, 16 and 42 and cannot anticipate such claims. *See In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir., 1990).

Accordingly, Applicants respectfully request that the rejection of Claims 1, 12, 15, 16 and 42 as being anticipated by Beerenwinkel *et al.* under 35 U.S.C. § 102(b) be withdrawn.

**M. The Rejection of Claims 32 and 33**

Claims 32 and 33 stand rejected allegedly because they are inherently anticipated by every wild type strain of HIV. Applicants respectfully submit that the rejection is obviated in view of the amendments to Claims 32 and 33. Accordingly, Applicants respectfully request that the rejection of Claims 32 and 33 under 35 U.S.C. § 102(b) be withdrawn.

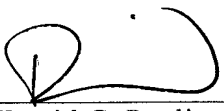
### CONCLUSION

Applicants believe that the claims of the instant application meet all of the conditions for patentability and are in condition for allowance. Accordingly, an early indication of the same is respectfully requested.

No fees, other than that for the Petition for Extension of Time, are believed to be due with this response. However, pursuant to 37 C.F.R. §1.136 (a)(3), the Commissioner is authorized to charge all required fees, or credit any overpayment, to Jones Day Deposit Account No. 50-3013 (949677-999065).

Respectfully submitted,

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